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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,896	10/19/2000	Mark H. Theno	1335.001US1	7633

7590

07/07/2003

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/07/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/691,896

Applicant(s)

THENO, MARK H.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-14,17-31 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) 38 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-14,17-31,40 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1, 3-8, 10-14, 17-31, 38-41 are pending. Claims 38-39 are withdrawn from consideration, as they are directed toward non-elected subject matter. The Amendment filed 2/24/03, Paper No. 11, amended claims 1, 10, 25, 29, 38 and 40.

Applicant's arguments with respect to claims 1, 3-8, 10-14, 17-31 and 38-41 have been considered but are moot in view of the new ground(s) of rejection.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/21/03 has been entered.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3-8, 10-14, 17-31, 40-41, drawn to a patch, classified in class 424, subclass 443.
- II. Claims 38-39, drawn to a kit, classified in class 206, subclass 570.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are distinct, as they have different modes of operation, different functions, and

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different effects. A patch is operated by applying it to a substrate, while a kit operates by holding something. The function and effect of a patch is to impart a therapeutic effect, while the function of a kit is to hold something.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Janal Kalis on 6/11/03 a provisional election was made without traverse to prosecute the invention of Group I, claims 1, 3-8, 10-14, 17-31, and 40-41. Affirmation of this election must be made by applicant in replying to this Office action. Claims 38-39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claims 5-6 and 41 are vague and indefinite, as they are confusing. Is not the vapor emitting portion the cellular portion? If they are distinct, how can the cellular portion and the pad be comprised of the same material (polyolefin)?

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-8, 10-12, 17-20, 23-27, 29-30, 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cartmell et al. (5,501,661) in view of Fischel-Ghodsian (5,455,043).

The instant invention is directed toward a patch comprising a base portion comprising a hydrogel, a cellular portion structure, comprising a foamed polyolefin, contacting the base portion, the cellular portion structure comprising a vapor emitting portion; and a vapor emitting material stored within the vapor emitting portion, and methods of releasing a vapor from such a patch.

Cartmell et al. teach a wound dressing product containing a porous layer. The wound dressing product comprises an optional release liner, an optional removable tab, and a wound dressing. The wound dressing comprises a thin-film layer, an adhesive layer, a porous backing layer, an optional support layer and a hydrogel material. The thin-film layer has a first side and an opposing second side and forms the outer surface of the dressing product. The adhesive layer is positioned on the second side of the thin-film layer. The backing layer is constructed of a porous material comprising a polyolefin foam. The porous backing layer has a first side and an opposing second side, and is adhered to the second side of the thin-film layer by the adhesive layer. The optional support layer is made from a material such as woven and nonwoven fabrics. The hydrogel material may be secured to the second side of the support layer. The permeable

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fabric of the support layer allows the hydrogel material to pass through to the first side of the support layer, resulting in the presence of the hydrogel layer on the first, as well as the second, side of the support layer. The optional release liner overlies the hydrogel material and is secured to the perimeter portion of the second side of the thin-film layer by means of the adhesive layer. The optional removable tab is interposed between the thin-film layer and the release liner. The porous layer is taught as having open spaces, thereby giving the layer its porosity. The reference lacks an explicit teaching of a cellular structure or a vapor emitting material stored within the vapor emitting portion. See Col. 1, line 59-Col. 3, line 20; Col. 5, line 28-Col. 9, line 23.

Fischel-Ghodsan teach patches comprising polyolefin foams, such as polypropylene foams and polyethylene foams. These foams are taught as having cellular structures that vary in size to increase or decrease porosity. See Col. 5, lines 14-25.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the polyolefin foams of Cartmell et al. as having a cellular structure, as taught by Fischel-Ghodsan because Fischel-Ghodsan teach polyolefin foams as having cellular structures as part of their form and because of the expectation of achieving a foam form that matches the rate of emission with the porosity of the cell sizes.

Though the reference does not explicitly state that vapor emitting materials are stored within the foam, the Examiner respectfully points out that it is implicit in the teachings of Cartmell et al., as the foam layer is the layer through which oxygen and other vaporpermeable substances are transferred from the wound to the environment. Additionally, while the reference does not implicitly teach two vapor emitting materials separately stored in two separate portions of the pad, the Examiner respectfully points out that Cartmell et al. teach that any

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vaporpermeable material from the wound travels through the foam layer, wherein the different materials can travel through different areas of the foam layer.

Claims 13-14, 21-22, 28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cartmell et al. in view of Fischel-Ghodsian as applied to claims 1, 3-8, 10-12, 17-20, 23-27, 29-30, 40-41 above, and further in view of Wick et al. (6,010,715).

Cartmell et al. and Fischel-Ghodsian are applied as discussed above. The references lack a teaching of the release layer being made of polyolefin, polyamide, cellulosic, or polyethylene terephthalate.

Wick et al. teach a transdermal patch. The backing layer is taught as being made of cellulose acetate, ethyl cellulose, polyethylene terephthalate and others. These compounds are taught as being made of a material that is substantially impermeable to the layer or layers with which it can be in contact. The patches are taught as being kept sealed in an air-tight pouch prior to use. See Col. 14, lines 34-65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the release liner of Cartmell et al. as being made of cellulose acetate, ethyl cellulose, or polyethylene terephthalate, as taught by Wick et al. because of the expectation of achieving a product that is impermeable to the hydrogel, thereby keeping the product intact.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the patches of the combined references as being kept sealed in an air-tight pouch prior to use, and thereby having to remove the patch from the seal for use, as taught by Wick et al., because of the expectation of achieving a patch that is sterile.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
June 11, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER
6/17/03